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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/619,216

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Laurent Verard

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EXAMINER

ROZANSKI, MICHAEL T

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

05/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/619,216	Applicant(s) VERARD ET AL.	
	Examiner MICHAEL T. ROZANSKI	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-28, 30-34, 44-49, 51, 52, 55-64 and 66-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-28, 30-34, 44-49, 51, 52, 55-64 and 66-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/6/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/6/09 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-28, 30-34, 63-64, and 66 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 22 has been amended to include a third icon that represents a path through the anatomy to the optimized site. This limitation is not supported by the specification. Rather, the specification is directed towards a projection icon that can determine where a catheter is

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traveling and how far or how much travel is necessary to reach a target if the catheter continues along its straight 174 or curved 182 trajectory (Figs 9 and 10 of Applicant's spec, and described in [0108,0109]). First, it is noted that straight trajectory 174 is only a portion of probe icon 172. This is contrary to the claim which reads that the icon is separate from an icon representing the instrument. However, it appears that curved icon 182 is described in the specification as a separate icon. Even if the claim is only directed to a curved icon, this does not represent a path through the anatomy to the optimized site. Rather, it represents the projected path of the catheter *if it continues along its current trajectory*. Continuing along a current trajectory will not necessarily lead to an optimized site and, therefore, the claimed limitation constitutes new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 68 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 68, it is unclear how the system "knows" if the instrument cannot navigate the anatomy. It appears from Applicant's specification that a 'tortuosity factor' is determined, but it is also unclear where this information comes from.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 11-20, 22-28, 30-34, 52, 55-64, and 66-67 are rejected under 35

U.S.C. 102(e) as being anticipated by Solomon (US pub 2003/0018251).

Solomon discloses cardiological mapping and navigation system and method including an imaging device that captures image data in response to a cardiac gating signal. This series of images produces a "cine" of the beating heart, which is then synchronized with the patient's ECG for the purpose of speeding up or slowing down the "cine" in accordance with the rate of the patient's beating heart [0032, 0053]. The imaging modality may be CT, MR, nuclear medicine, or ultrasound [0030]. Position sensors 12 and electrodes 14, 24 are located on the lasso catheter 10 and the ablation catheter 11. The position sensors comprise coils 13, 23 to perform the sensing [0041]. A computer 15 calculates the position and orientation of the coils and displays in a superimposed manner the positions of the catheters on the gated images [0046]. In addition to superimposing the catheter positions, Solomon discloses superimposing a computer generated electrophysiological map of the heart on the gated images so that the electrical activity of the heart can be viewed in relation to the true structure of the heart [0014]. Such can be used to represent an 'optimized' or desired site for the instrument. Furthermore, the patient is registered with the gated images, which is

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accomplished by using external fiducial markers [0037] or by defining several points from within the patient's heart [0038].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 44-49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solomon et al in view of Dekel et al (US 6,203,497 -of record).

Solomon et al disclose all features of the current invention as described above, but does not disclose displayed an image from a virtual viewpoint of the tracked instrument. In the same field of endeavor, Dekel et al teach of providing ultrasound images from the perspective or viewpoint of the instruments (col 2, lines 34-39). It would have been obvious to modify Solomon et al, to include means to view image data from a perspective of an instrument as taught by Dekel et al, in order to allow the operator to more easily visualize the course of the instrument in the body (col 2, lines 3-10).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-44 of copending Application No. 10/299,969. Although the conflicting claims are not identical, they are not patentably distinct from each other because Hunter et al. substantially claims all features in obvious alternate variations and groupings. Hunter et al. claims an image guided catheter navigation system for guiding a catheter through a region of a patient, comprising an imaging device selected from a number of imaging techniques, a tracking device, a controller, and a display. Hunter et al. also claims a method comprising receiving a cyclic physiological signal and time gating the detection of the location of the catheter, as well as time gating the generation of the image.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 44-49 and 51 are provisionally rejected on the ground of obviousness-type double patenting as being unpatentable over claims 1-26 of US Patent No. 6,892,090. Although the conflicting claims are not identical, they are not patentably distinct from each other because '090 substantially claims all features in obvious alternate variations and groupings. '090 features a surgical navigation system including a surgical instrument, a timing signal generator correlating with an anatomical function of the patient, a tracking subsystem, a data processor that renders an image from a perspective of the surgical instrument, and a display with indicia representing the instrument.

Claims 44-49 and 51 are provisionally rejected on the ground of obviousness-type double patenting as being unpatentable over claims 1-12 and 14-51 of US Application No. 11/068,342. Although the conflicting claims are not identical, they are not patentably distinct from each other because '342 substantially claims all features in obvious alternate variations and groupings. '342 features a surgical navigation system including a surgical instrument, a timing signal generator correlating with an anatomical function of the patient, a tracking subsystem, a data processor that renders an image from a perspective of the surgical instrument, and a display with indicia representing the instrument.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 4/6/09 have been fully considered but they are not persuasive. In regard to claim 1, Applicant argues that Solomon does not disclose displaying an icon superimposed on the image data that represents the instrument and the displaying a separate icon superimposed on the image that represents an estimated optimized site on the image data. Examiner disagrees. Icons 12', 22' are superimposed on the image and represent the location of the catheter because position sensors 12, 22 are located on the catheters. Further, Examiner maintains that the EP map is a separate icon superimposed on the image data and represents an estimated optimized site because electrical information would help determine an optimized site. This point was also discussed in the previous rejection. It is noted that newly added claim 68, which depends from claim 1, would be allowable if incorporated into claim 1 and the 112 rejection is overcome. Here, the Examiner suggests claiming that a 'tortuosity factor' is determined, how the factor is determined (i.e. from what data), and how the system 'knows' if the instrument can navigate the anatomy.

In regard to claim 22, it is noted that the claim is rejected for the reasons given above in the art rejection in view of the 112 new matter rejection. Examiner suggests claiming subject matter that is supported by the specification, specifically from [0108,0109].

In regard to claim 44, the scope is different due to the amendment and is now rejected over Solomon in view of Dekel et al, which clearly teaches displaying image

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data from the perspective of an internal instrument. In addition, it appears this concept has also been claimed in Applicant's other applications. Two new double patenting rejections are presented.

In regard to claim 52, Applicant argues that Solomon delivers an ablation energy, and not a cardiac lead. However, the ablation energy is delivered through an electrode. In the art, an electrode and lead are each generally regarded as a wire and, therefore, are structurally indistinguishable. The rejection of Solomon et al is maintained.

In regard to claim 63, Applicant is directed to the comments regarding claim 22.

It is noted that Applicant requested the double patenting rejection with copending application number 10/299,969 be held in abeyance. However, per MPEP 804 I.B1, it is proper to maintain this rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL T. ROZANSKI whose telephone number is (571)272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

MR